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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/633,626	08/05/2003	Gregory M. Glenn	056707-5009-01	056707-5009-01 6381	
9629	7590 06/05/2006		EXAMINER		
MORGAN LEWIS & BOCKIUS LLP			KIM, YUNSOO		
	SYLVANIA AVENUE N ON, DC 20004	W	ART UNIT	PAPER NUMBER	
,			1644		
			DATE MAILED: 06/05/200	DATE MAILED: 06/05/2006	

Please find below and/or attached an Office communication concerning this application or proceeding.

## Advisory Action Before the Filing of an Appeal Brief

Application No.	Applicant(s)		
10/633,626	GLENN ET AL.		
Examiner	Art Unit		
Yunsoo Kim	1644		

The MAILING DATE of this communication appears on the cover sheet with the correspondence address  "Itel REPLY FILED 05 May 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.  Itel Reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application applicant must timely file one of the following replies; (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance, (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 4.13.1; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.14. The reply must be filed within one of the following a Request for Continued Examination (RCE) in compliance with 37 CFR 1.14. The reply must be filed within one of the following a Request for Continued Examination (RCE) in compliance with 37 CFR 1.14. The reply must be filed within one of the following a Request for Continued Examination (RCE) in compliance with 37 CFR 1.14. The reply must be filed within one of the following a RCE of the Appeal (RCE) and the RCE of RC		Yunsoo Kim	1644	
HE REPLY FILED <u>05 May 2005</u> FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.    The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCC) in compliance with 37 CFR 1.14. The reply must be filled within one of the following imperiods:  a) □ The period for reply expires <u>3</u> months from the mailing date of the final rejection.  b) □ The period for reply expires <u>3</u> . months from the mailing date of the final rejection.  Examiner Note: I box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN CHARGING FIRM CHECKTON SOM FIPM REPLACETION. See MFEP FOB 07(f).  Citatorsion of MONTHS OF THE FIRM. REJECTION. See MFEP FOB 07(f).  Citatorsion of MONTHS OF THE FIRM. REJECTION. See MFEP FOB 07(f).  Citatorsion of MONTHS OF THE FIRM. REJECTION. See MFEP FOB 07(f).  Citatorsion of MONTHS OF THE FIRM. REJECTION. See MFEP FOB 07(f).  Citatorsion of MONTHS OF THE FIRM. REJECTION. See MFEP FOB 07(f).  Citatorsion of MONTHS OF THE FIRM. REJECTION. See MFEP FOB 07(f).  Citatorsion of MONTHS OF THE FIRM. REJECTION. See MFEP FOB 07(f).  Citatorsion of MONTHS OF THE FIRM. REJECTION. See MFEP FOB 07(f).  Citatorsion of MONTHS OF THE FIRM. REJECTION. See MFEP FOB 07(f).  Citatorsion of MONTHS OF THE FIRM. REJECTION. See MFEP FOB 07(f).  Citatorsion of MONTHS OF THE FIRM. REJECTION. See MFEP FOB 07(f).  Citatorsion of the men proper seed of the final rejection. See 30 CFR 1.130 (a) men proper seed of the final rejection. See 30 CFR 1.130 (a) men proper seed of the final rejection. See 30 CFR 1.130 (a) men proper seed of the final rejection. See 30 CFR 1.130 (a) men proper seed seed of the final rejection. See 3	The MAILING DATE of this communication appe	ars on the cover sheet with the d	correspondence add	ress
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a)	1.  The reply was filed after a final rejection, but prior to or or this application, applicant must timely file one of the follow places the application in condition for allowance; (2) a Not a Request for Continued Examination (RCE) in compliance	the same day as filing a Notice of wing replies: (1) an amendment, aff tice of Appeal (with appeal fee) in a	Appeal. To avoid aba idavit, or other evider compliance with 37 C	nce, which FR 41.31; or (3)
no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.  Examiner Note: It box 1 is checked, check either box (a) or (b). ONLY-OHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FIRAL REJECTION. See MPEP 706.07(f).  Extensions of time may be obtained under 37 CFR 1.136(a) and the appropriate extension fee ave been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee ave been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee ave been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee and the period of the filed from the period of the filed with the period set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, any reduce any earned palant term adjustment. See 37 CFR 1.794(b).  OTHOR NOTICE OF APPEAL  The Notice of Appeal was filed on A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).  MENDMENTS  The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because (a) They raise the issues of new matter (see NOTE below);  (b) They raise the issue of new matter (see NOTE below);  (c) They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  (d) They are not deemed to place the application in better form for appeal by materially reducing	a) The period for reply expires 3 months from the mailing date	of the final rejection.		
ave been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee and 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as et forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, any reduce any earned patent term adjustment. See 37 CFR 1.704(b).  OTICE OF APPEAL    The Notice of Appeal was filed on A brief in compliance with 37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).  MENDMENTS   Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).  MENDMENTS   The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because (a) They raise new issues that would require further consideration and/or search (see NOTE below);	no event, however, will the statutory period for reply expire I Examiner Note: If box 1 is checked, check either box (a) or TWO MONTHS OF THE FINAL REJECTION. See MPEP 7	ater than SIX MONTHS from the mailin (b). ONLY CHECK BOX (b) WHEN THI 06.07(f).	g date of the final reject E FIRST REPLY WAS F	ion. ILED WITHIN
	nave been filed is the date for purposes of determining the period of ex under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the set set forth in (b) above, if checked. Any reply received by the Office later may reduce any earned patent term adjustment. See 37 CFR 1.704(b)	tension and the corresponding amount shortened statutory period for reply orig r than three months after the mailing da	of the fee. The approprinally set in the final Offi	iate extension fee ice action; or (2) as
(a)	2. The Notice of Appeal was filed on A brief in comp filing the Notice of Appeal (37 CFR 41.37(a)), or any exte	nsion thereof (37 CFR 41.37(e)), to	avoid dismissal of th	ns of the date of se appeal. Since
(a)	3. The proposed amendment(s) filed after a final rejection,	but prior to the date of filing a brief,	will not be entered b	ecause
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.  NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).  ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  ☐ Applicant's reply has overcome the following rejection(s):	(a) They raise new issues that would require further co	nsideration and/or search (see NO	TE below);	
NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).  The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  Applicant's reply has overcome the following rejection(s):	(c) They are not deemed to place the application in bet		ducing or simplifying	the issues for
The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324). Applicant's reply has overcome the following rejection(s):	(d) They present additional claims without canceling a	corresponding number of finally rej	ected claims.	
Applicant's reply has overcome the following rejection(s):  Newly proposed or amended claim(s) would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  For purposes of appeal, the proposed amendment(s): a) ⊠ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  The status of the claim(s) is (or will be) as follows:  Claim(s) allowed: None.  Claim(s) objected to: None.  Claim(s) rejected: 2-7,11,31,4,16,19,31,38 and 46-60.  Claim(s) withdrawn from consideration: None.  IFFIDAVIT OR OTHER EVIDENCE  ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  M The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached. ECQUEST FOR RECONSIDERATION/OTHER  Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s)	NOTE: See Continuation Sheet. (See 37 CFR 1.1	16 and 41.33(a)).		
Newly proposed or amended claim(s) would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  For purposes of appeal, the proposed amendment(s): a) \( \times \) will not be entered, or b) \( \times \) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended. The status of the claim(s) is (or will be) as follows: Claim(s) allowed: \( \frac{None}{None} \) Claim(s) objected to: \( \frac{None}{None} \) Claim(s) objected to: \( \frac{None}{None} \) Claim(s) withdrawn from consideration: \( \frac{None}{None} \) Claim(s) withdrawn from consideration: \( \frac{None}{None} \) The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will \( \frac{not}{not} \) be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will \( \frac{not}{not} \) be entered because the affidavit or other evidence failed to overcome \( \frac{all}{not} \) rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached. SEQUEST FOR RECONSIDERATION/OTHER  The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.  Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s)	4. $\square$ The amendments are not in compliance with 37 CFR 1.1:	21. See attached Notice of Non-Co	mpliant Amendment	(PTOL-324).
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<ol> <li>The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.</li> <li>Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s).</li> </ol>		n of the status of the claims after e	ntry is below or attach	ned.
2. Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s)	11.   The request for reconsideration has been considered but	it does NOT place the application in	n condition for allowa	nce because:
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Continuation of 3. NOTE: The limitation recited in claims 63 and 64, "physically" or "chemically" to enhance immunization was not searched previously

Continuation of 11. does NOT place the application in condition for allowance because:

claims 2-7, 11, 13, 14, 16, 19, 31, 38, 46-60 stand rejected under 35 USC 112, 1st paragraph for the reasons set forth in the office action mailed 1/10/06. Applicants' argument and the declaration by Dr. Epperson filed 5/5/06 have been fully considered but they were not persuasive. Applicants traversed the rejection based on that the method of inducing an immune response comprising "dry " formulation is enabled. However, the pretreatment recited by the claim encompasses alcohol treatment, as applicant admits in p. 10 of the response filed 5/5/06, the formulation applied to alcohol pretreated area would be wet. In addition, the declaration by Dr. Epperson filed 5/5/06 discloses that there is no hydration or pretreatment was involved. However, the specification (p. 7-8) includes chemical or physical penetration enhancement and abrading before applying the antigenic formulation (e.g. shaving of skin) was performed in examples 1-7 or in declaration. Thus, the method of inducing immune response by applying a dry formulation onto intact skin without pretreatment is not enabled.

Claims 2-7, 11, 13, 14, 16, 19, 31, 38, 46-60 stand rejected under 35 U.S.C. 102(e) as being anticipated by U.S.Pat. No. 6,797,276 for the reasons set forth in the office action mailed 1/10/06. Applicants' arguments filed 5/5/06 hav been fully considered but they were not persuasive. Applicants' argue that ther reference teaches the different invention because applying dry formulation onto pretreated area would yield wet formulation. However, the '276 patent teaches the method of inducing immune response by dry formulation (claims 1-11 and col. 8, line 25) and pretreating by alcohol as the claimed invention. Thus, reference teachings anticipate the claimed invention.

Claims 2-5, 11, 13, 14, 31, 38, 46-48, 50-54, 57 and 58 stand rejected on the ground of nonstatutory obviousness type double patenting as being unpatentable over claims 1-11 of US Pat. No. 6,797,276.

Applicants' arguments filed 5/5/06 hav been fully considered but they were not persuasive. Applicants' argue that the reference teaches the different invention because applying dry formulation onto pretreated area would yield wet formulation. As discussed above, the '276 patent teaches the method of inducing immune response administering antigen and adjuvant to skin.

In view of Applicant's arguments and remark, the rejection under 35. U.S.C.112 first paragraph regarding new matter set forth in the previous office action mailed 1/10/06 (section 7) has been withdrawn.

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
SUPERVISORY CENTER 1600

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